Effect of a primary care-based psychological intervention on symptoms of common mental disorders in Zimbabwe: a randomized clinical trial

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63 **Key Points**

64 **Question**: Does a lay health worker-delivered psychological intervention improve symptoms of
65 depression and anxiety in Zimbabwe?

66 **Findings**: In a cluster-randomized clinical trial of 573 randomized patients with common mental
67 disorders and symptoms of depression, the group who received the intervention had significantly
68 lower symptom scores after 6 months compared to a control group who had enhanced usual care.

69 **Meaning**: The use of lay health workers in resource-poor countries like Zimbabwe may be effective
70 primary-care-based management of common mental disorders.

71

72 **Abstract**

73 **Importance:** Depression and anxiety are common mental disorders globally, but rarely recognized or
74 treated in low-income settings. Task-shifting of mental health care to lay health workers (LHWs) might
75 decrease the treatment gap.

76 **Objective:** To evaluate the effectiveness of a culturally-adapted psychological intervention for common
77 mental disorders delivered by LHWs in primary care .

78 **Design, setting and participants:** Cluster-randomized clinical trial with 6 months follow-up conducted from
79 1 September 2014-25 May 2015 in Harare, Zimbabwe. Twenty four clinics were randomised 1:1 to the
80 intervention or enhanced usual care. Participants were clinic attenders aged $\geq$18 years who screened
81 positive for common mental disorders on the locally-validated Shona Symptom Questionnaire (SSQ-14).

82 **Interventions:** The Friendship Bench intervention comprised 6 sessions of individual problem-solving
83 therapy delivered by trained, supervised LHWs plus an optional 6-session peer support program. The
84 control group received standard care plus information, education and support on common mental
85 disorders.

86 **Main outcome measures:** Primary outcome was common mental disorder measured at 6 months as a
87 continuous variable via the SSQ-14 score, with a range of 0 (best)to 14 (worst) and a cut-point 9. The

secondary outcome was depression symptoms measured as a binary variable with the Patient Health Questionnaire-9 (PHQ-9), with a range of 0 (best) to 27 (worst) and a cut-point 11). Outcomes were analyzed by intention-to-treat.

Results: Among 573 randomized patients (286 in the intervention group and 287 control group), 495 (86.4%) were women, median age was 33 years (interquartile range 27-41 years), 238 41.7% were HIV positive, and 521 (90.9%)) completed follow up at 6 months. Intervention group participants had fewer symptoms than control group participants on the SSQ-14 (3.81 (95% CI 3.28, 4.34) vs 8.90 (95% CI 8.33, 9.47), adjusted mean difference (AMD)=-4.86; 95% CI -5.63, -4.10, p<0.001; adjusted risk ratio(ARR)=0.21, 95% CI 0.15, 0.29, p<0.001). Intervention participants also had lower risk of symptoms of depression (13.7% vs 49.9%, ARR=0.28, 95% CI 0.22, 0.34, p<0.001).

Conclusions and Relevance: Among individuals screening positive for common mental disorders in Zimbabwe, LHW-administered, primary care-based problem solving therapy with education and support compared with standard care plus education and support resulted in improved symptoms at 6 months. Scaled-up integration of this intervention should be evaluated.

Trial registration: PACTR201410000876178.
http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_windowLabel=BasicSearchUpdateController_1&BasicSearchUpdateController_1_actionOverride=%2Fpageflows%2Ftrial%2FbasicSearchUpdate%2FviewTrail&BasicSearchUpdateController_1id=876

Introduction

Depression and anxiety are the most common mental disorders globally and major causes of disease burden in Sub-Saharan Africa[1,2]. Few people with common mental disorders in low-income settings have access to effective treatments[3]. When left untreated, common mental disorders can impair role functioning, self-care and adherence to treatments, and are associated with reduced productivity and increased healthcare costs[4].

Zimbabwe has a large treatment gap for common mental disorders, with only 10 psychiatrists serving a population of 13 million. Prevalence of common mental disorders above 25% has been reported among adult primary care attendees[5-8] but there are no psychological services in primary health care. A potentially feasible approach to improve this situation would require task-shifting; allowing properly trained and supervised lay health workers (LHWs) in primary care to contribute to the treatment of common mental disorders. Mental health interventions delivered by LHWs must be simple and brief so that they can effectively provide care for a range of common mental health problems[9]. Problem solving therapy is a brief psychological therapy which has been shown to be effective for many common mental health conditions seen in primary care in high-income settings[10,11]. A problem-solving therapy intervention locally termed 'The Friendship Bench' has been shown in piloting to be acceptable for LHWs to deliver in Zimbabwe with promising results[7,12,13]. In the Friendship Bench model, trained and supervised LHWs provided 6 sessions of individual problem-solving therapy to all patients with common mental disorders and referred those not improving or with suicidal ideation to their immediate supervisors for treatment adjustments[14]. Participants were also invited to an optional 6-session peer-led group support program. The aim of this trial was to evaluate the effectiveness of this culturally adapted intervention for common mental disorders delivered by existing LHWs in primary care in Harare, Zimbabwe.

Methods

Trial Design: The study protocol has been published previously[14] and is available in the Supplement. We conducted a cluster-randomized clinical trial in 24 primary care clinics (clusters) in Harare, Zimbabwe, with a 1:1 allocation ratio. A cluster design was used because the intervention involved training staff at clinic level.

The protocol was approved by the ethics committees of the Medical Research Council of Zimbabwe and London School of Hygiene and Tropical Medicine. Eligible participants provided written informed consent to participate in the trial.

Setting: In each of the 12 districts of Harare there were 5-8 clinics of varying size. The largest, known as polyclinics, provided broad acute and chronic services and maternity care and were staffed by up to 14 nurses, 8 nurse aides and 12 LHWs. A physician visited every 2 weeks. Small satellite clinics provided acute services and home-based nursing care and were staffed by 1-2 nurses and nurse aides and 3-4 LHWs. From 42 primary care clinics in Harare, we selected 24 clinics of the largest clinics that were in accessible locations with mobile network coverage, had reliable data on stratification variables, and were willing to be involved in the study.

Randomization and allocation concealment: Clinics were randomized in a 1:1 ratio within 5 strata based on HIV status, housing density, clinic size, and sex of patients. Restricted randomization was used to minimize imbalance in key factors (HIV prevalence, clinic size, staff size, and sex ratio) as described previously[14]. The research assistants responsible for outcome assessment were masked to the allocation.

Participants: All adults attending trial clinics during a 2-week period were informed about the study, including explanation about common mental disorders and how these can affect other conditions, such as hypertension, HIV, and diabetes. Following informed consent for screening, patients completed the Shona Symptom Questionnaire (SSQ-14), a locally validated screening tool for common mental disorders[15], re-validated for this study population[8]. On each day of screening, computer-generated preprinted random numbers were used to select clinic attenders based on their queue position number. All persons randomly selected who were aged $\geq$18 years and resident in the area were eligible for further assessment if they screened positive (≥9) on the SSQ-14. Screening ended when 24 participants had been enrolled. All persons

who were unable to comprehend the nature of the study in either English or Shona (local language), had suicidal intent, end-stage AIDS, were currently in psychiatric care, were pregnant or up to 3 months post-partum, presented with current psychosis, intoxication, and/or dementia were excluded. Those excluded for psychiatric reasons were referred to a tertiary health care facility in Harare. Those with suicidal ideation on the SSQ-14 but not subsequently assessed as having suicidal intent were included in the study.

Intervention: The Friendship Bench intervention has been developed over a 20-year period from community research[16-18], as described previously[14]. This intervention is problem-solving therapy, in which the patient identifies a problem (eg, unemployment) rather than a diagnosis or symptom. is the intervention has been shown to be feasible and acceptable in this resource-poor setting[7,13]. The psychological approach of problem-solving therapyworks through enabling a more positive orientation towards resolving problems and empowering people to have a sense of greater coping and control over their lives[19]. In practical terms participants were taught a structured approach to identifying problems and finding workable solutions[20]. Lay health workers followed a detailed script contained in a manual to conduct 6 sessions on a bench located in a discreet area outside the clinic[7]. The first session includes three components named Opening the Mind (*kuvhura pfungwa*), Uplifting (*kusimudzira*) and Strengthening (*kusimbisa*)[12] with subsequent sessions building on the first[21]. Opening the mind refers to the therapeutic process by which, through asking questions, clients were encouraged to open their minds to identify their problems, choose one to work on, identify a feasible solution, and agree an action plan through an iterative process guided by the LHWs. The care model was driven by a trained and supervised LHW attached to the clinic and employed by the local health authority. After 6 sessions of individual therapy, the LHW referred those not improving or with suicidal ideation to a supervisor trained in mental health to re-assess and manage the case if needed. Participants in the intervention group received up to 6 text messages and/or phone calls during the intervention, which reinforced the problem-solving therapy approach and encouraged clients, particularly those attending less than 3 sessions during the first 4 weeks, to follow their action plan. As part of the improved management program, clients were re-assessed by the LHW after the third session using the SSQ-14, and those whose score had worsened by 1 or more or who

had suicidal ideation were assessed by a psychiatrist. These results were not used for research purposes. If participants missed a session, the LHWs followed up with a phone call and/or a home visit if there was no response.

All LHWs in the study were female with a mean age of 53, mean of 10 years of education, able to use a mobile phone and residing near their respective clinic. They were supervised and supported by trained senior health promotion officers who were part of the existing supervisory systems for LHWs. The LHWs were trained over 9 days using a manual written by the Friendship Bench team[21]. Topics included Common mental disorders, counselling skills, problem-solving therapy , and self-care. All sessions were audio-recorded for fidelity, and assessed using a checklist to ensure LHWs had covered all the critical components.

After 4 individual sessions, all intervention group participants were invited to join a peer-led group called Circle Kubatana Tose, or "holding hands together" which was part of the intervention as described in the protocol[14]. This component provided group support from women who had attended the Friendship Bench prior to the trial and who had received basic group management training by study clinicians. These weekly meetings consisted of sharing personal experiences while crocheting a bag from recycled plastic materials, the latter being an income-generating skill for participants through selling the bags. Participants in the intervention group were also offered enhanced usual care.

Enhanced Usual Care (EUC): The control group received the standard usual care consisting of a nurse-led evaluation, brief support counselling and option for medication, as well as information, education and support on common mental disorders including assessment for anti-depressant medication prescribed by the clinic nurse and/or referral to a psychiatric facility if needed. Participants also received 2-3 supportive SMS messages or calls with the last message being a reminder to attend the 6-months assessment. Participants in both groups were not aware which group was the intervention. Further details of both the intervention and EUC have been previously reported[14].

Outcomes: The primary outcome was SSQ-14 symptom score[15] measured as a prespecified continuous variable at 6 months. The SSQ-14 was developed and validated in Zimbabwe and has good psychometric

properties in a primary care population. It is scored from 0-14 with higher score meaning worse symptoms, and a cut-point of ≥9 has 84% sensitivity and 73% specificity for any CMD.[8] The secondary outcome was prevalence of symptoms of major depressive disorder based on the Patient Health Questionnaire 9 (PHQ-9), defined as a total score ≥11 on a range of 0-27, fulfilling criteria through a diagnostic algorithm[22] and with higher scores meaning worse symptoms. The protocol originally had the PHQ-9 cut-point at 9 (Supplement). However, this was altered after validation of the PHQ-9 in the study population found that 11 was a more appropriate cut-point.[14] Analysis of PHQ-9 scores as binary variables was prespecified in the trial protocol; however, analysis of PHQ-9 scores as continuous variables was not prespecified. Tertiary outcomes were generalized anxiety disorder score (GAD-7)[8,23] on a range of 0=best-12; WHO-DAS 2.0 12-item score for disability (range 0=best-48); and EQ-5D total score for health-related quality of life(range 0=best-25).

Sample size: A sample of 24 clinics, each with 24 participants provided 80% power to detect an effect size (standardised mean difference) in SSQ-14 score of 0.75 at follow-up, with 80% power and Type I error of 5%, assuming a between-cluster coefficient of variation (k)=0.2. The effect size was based on a recent systematic review of LHW interventions with severity of CMD as an outcome[14,24].

Statistical analysis: Data were collected using tablet computers, uploaded to a secure server using cloud computing technology and exported to Stata 14.0 for cleaning and analysis. Baseline characteristics were compared by trial group and follow-up status. Analyses were intention-to-treat and followed a pre-specified analysis plan according to CONSORT guidelines[25], with Type 1 error of 0.05 and 2-sided testing. Due to a high follow-up response rate (91%) we used complete case analysis and missing data were not imputed. Analyses were based on cluster-level summary measures to take clustering by site into account, because individual-level regression methods are not robust when there are few clusters[26]. For continuous outcomes with normally distributed residuals, the intervention effect was estimated as the difference in mean scores between groups using linear regression of the mean score (adjusted for HIV status, sex, baseline SSQ-14 score, age and education (education appeared imbalanced between groups at baseline). An approximate variance was obtained from the residual mean square from a 2-way ANOVA of mean score

on strata and group. The 95% CI was estimated from this variance with a stratified t-test with 18 degrees of freedom. For binary outcomes, the measure of effect was the prevalence ratio, analysed by analogous methods using logistic regression. Pre-defined sensitivity analyses included adjustment for the following factors: age, sex, HIV prevalence and baseline SSQ-14 score, and effect-modification by HIV status, sex, and baseline symptom severity. Education was added to the model after examining baseline characteristics by arm. Effect-modification was assessed by fitting an interaction term between intervention group and the potential effect modifier on the cluster-level regression analysis, with p-value estimated by the t-test using robust standard errors.

Results

Study Participants: Across 24 clinics 2527 people were assessed for eligibility (Figure 1 and supplement table 1) and 1854 (73.4%) were excluded. The main reason for exclusion was an SSQ-14 score below 9 (n=1550) followed by non-residence in the locality (n=128). Of 673 people eligible for the study, 100 (15%) did not consent, leaving 573 participants enrolled (287 in the intervention group and 286 in the EUC group). Recruitment took place from September to December 2014 (median 4 days of screening per clinic). The mean number of participants per cluster was 23.9 (range 22-26). Most participants were female (86.4%), married (67.5%), with a median age of 33 years (interquartile range 27-41) (Table 1). The mean SSQ-14 score at baseline was almost the same across groups [10.4 (SD 1.33) and 10.5 (SD 1.33)] (Table 1). HIV status was known for 498 (87.3%) participants, and prevalence was high (41.7%), as was the proportion with suicidal ideation (13.1%). Participants in the intervention group were more likely to be female, younger and better educated, and less likely to be HIV positive. At enrolment, most participants (n=431, 75.1%) listed $\geq$3 problems that they were experiencing, with 74.1% reporting physical illness, 70.1% domestic violence/upheaval, and 66.2% loss of income. Prevalence of hypertension was 9.6% and 1.6% had diabetes.

Overall, 521 participants (91%) completed a 6-month follow-up interview (Figure 1), with similar follow-up in men and women (92% and 91%). The median time between enrolment and follow-up was 171 days (IQR 166-176) in the intervention group and 173 days (IQR 168-176) in the EUC group.

Outcome evaluation: The primary outcome of SSQ-14 scores for common mental disorders was lower in the intervention than in the control group (mean 3.81 (95% CI 3.28-4.34) vs 8.90 (95% CI 8.33-9.47); adjusted mean difference (AMD) in SSQ-14 score=-4.86; 95% CI -5.63, -4.10; p<0.001; Table 2). The prevalence ratio for symptoms of depression via prespecified binary variable analysis was lower in the intervention group than in the control group (13.7% vs 49.9%, adjusted rate ratio (ARR)=0.28, 95% CI 0.22, 0.34, p<0.001). Similarly, there was improvement in depression symptoms as measured by non-prespecified continuous variables for the PHQ-9 scores (AMD=-6.36, 95% CI -6.45, -5.27; p<0.001). There was also improvement in the tertiary outcomes: symptoms of generalized anxiety measured by GAD-7 (AMD=-5.73, 95%CI -6.61, -4.85; p<0.001); disability measured by WHO-DAS (AMD=-6.08, 95%CI -7.46, -4.71; p<0.001); and health-related quality of life measured by EQ-5D scores (AMD=0.12, 95%CI 0.08, 0.17; p<0.001) (Table 2). The prevalence of depression symptoms, anxiety symptoms and disability were each lower in the intervention group compared to the control at follow-up (adjusted risk ratios: PHQ-9 diagnostic algorithm=0.23, 95% CI 0.15, 0.33; GAD-7=0.26, 95% CI 0.19, 0.35; SSQ-14=0.21, 95% CI 0.15, 0.29; WHO-DAS=0.27, 95% CI 0.16, 0.44; Table 2). There was some evidence of a stronger intervention effect among participants with a higher baseline SSQ-14 score (SSQ-14 $\geq$11 vs <11) for tertiary outcomes (GAD-7, p-interaction=0.02; WHO-DAS, p-interaction=0.02) but not for SSQ-14 (p-interaction=0.19), PHQ-9 (p-interaction=0.10) or EQ-5D (p-interaction=0.20) (Figure 2). Following sensitivity analysis, there was no evidence of effect-modification by HIV status or sex for any of the outcomes. The coefficient of variation (k) was 0.21 for the SSQ-14 and 0.24 for the PHQ-9. Missing outcome was associated with baseline SSQ, PHQ-9 and WHO-DAS scores. Baseline SSQ score was already adjusted for, and adjusting for baseline PHQ-9 and WHO-DAS had no effect on any results. The complete-case analysis should therefore be unbiased. There was no evidence of harm associated with the intervention. At follow-up, 32 participants (12.3%) in the control group and 6 (2.3%) in the intervention group were identified as having suicidal ideation.

Adherence to the intervention: The number of problem-solving therapy sessions attended was ascertained for 267 (93.4%) participants in the intervention group. Each session lasted approximately 30-45 minutes with the first session lasting about 1 hour. The median number of sessions received was 5 (IQR 4-6) and 97 participants (39.9%) received all 6 sessions. Sessions were a median 3 days apart (IQR 2-4). Data on participation in the peer support group was available for 274 participants, and of these, 187 (68.3%) attended at least 1 meeting. At follow-up 8.1% of control participants and 5.4% of intervention participants reported receiving counselling in the previous 6 months, and 11.1% of control participants and 7.7% of intervention participants reported visiting a spiritual healer. Fifteen intervention group participants and 34 in the control group were referred to tertiary care and prescribed fluoxetine.

Discussion

Among individuals screening positive for common mental disorders in Zimbabwe, LHW administration of a primary care-based problem solving therapy with education and support compared with standard care plus education and support resulted in improved symptomatic outcomes. There was little evidence that this effect was moderated by severity of symptoms as measured with the SSQ-14 or PHQ-9, but some evidence of an interaction for tertiary outcomes (statistically significant (p=0.02) for WHO-DAS and GAD-7 but not for EQ-5D) in which those with more severe symptoms at baseline had better outcomes, as seen in previous trials[27].

Our findings are consistent with evidence on problem-solving therapy from high income countries[11]. Problem-solving therapy is an attractive option in a low resource context because unlike cognitive behaviour therapy it does not require extensive training or complex skills. The trial showed benefits with peer support as a voluntary option but was not able to isolate the mechanism of action or the relative contribution of each component. Of note, peer support meetings continued after study closure and were subsequently integrated into clinic activities.

A strength of our study was the use of tools with local cultural validity together with well-known measures that had been rigorously tested in our setting[8] . The intervention, developed in consultation with

stakeholders, was designed to be delivered with available resources in the primary health care system[12]. Having a contextually relevant cadre of health workers to deliver the psychological therapy who were perceived as mature and trustworthy by the community is likely to have been important in forming a strong therapeutic alliance[13,28]. The study was well powered, outcome measures were locally validated, the intervention was carefully monitored, and attrition rates were very low. Friendship Bench delivered by LHWs was effective at reducing severity of common mental disorders as measured by a range of validated tools. Several successful psychological interventions have been delivered by LHWs in Africa but none has been scaled up[29-32]. Designing an intervention that is delivered within the health system and using existing workers is key to ensuring future scalability.

Limitations: This trial had several limitations. Endpoints were at 6 months and sustainability of effect beyond this time is unknown. There were few men in the study, as they are less likely to attend primary care clinics. However, in this trial men were as likely as women to join the peer support groups and to remain in follow-up. The program scale-up includes male-only peer support groups. Research assistants conducting follow-up interviews in the clinics could have ascertained allocation by the presence of the Bench, but we attempted to minimize bias by keeping research assistants independent of intervention delivery and implementation. Some symptoms such as insomnia and inability to function could be due to distress as opposed to depression, however, the use of validated outcome tools for a range of common mental disorders should have minimised this risk. Few participants in either group reported receiving any form of counselling in addition to the trial, but participants may have sought help elsewhere. We were unable to collect reliable information on the prescription of medications, but we do not expect this to be high based on our previous research[7] and the small number of people referred to tertiary care across both groups. Similarly, we were unable to ascertain whether those stepped up to see a nurse or specialist received any other more intensive treatment apart from fluoxetine. At the initial assessment the proportion of individuals regarded as high-risk were comparable across groups. More people were referred to tertiary care in the control than the intervention group so any additional treatment would have reduced

the differences observed between groups. The intervention group had a lower proportion of people assessed as at higher risk of suicide at follow-up. However, as with many cluster-randomized trials with relatively few clusters[26], there was some imbalance between groups which was adjusted for in the analysis. Finally, this trial included a combination of supportive therapies (problem solving therapy and the peer-led group) and did not permit isolated assessment of the effect of each specific therapy.

Conclusions

Among individuals screening positive for common mental disorders in Zimbabwe, LHW-administered, primary-care-based problem solving therapy with education and support compared with standard care plus education and support resulted in improved symptoms at 6 months. Scaled-up primary care integration of this intervention should be evaluated.

Abbreviations

CBT, Cognitive Behavioural Therapy; EUC, Enhanced Usual Care; LHW, Lay Health Worker; PHQ, Patient Health Questionnaire; SSQ-14, Shona Symptoms Questionnaire 14.

Competing interests

The authors declare that they have no competing interests.

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459 **Table 1: baseline characteristics of study participants by group**

Variable	Variable parameters	Intervention group (N=286)	Control group (N=287)
Gender - no. (%)			
Male		32 (11.2)	46 (16.0)
Female		254 (88.8)	241 (84.0)
Age group (years) – no. (%)			
18-24		64 (22.4)	43 (15.0)
25-34		107 (37.5)	112 (39.0)
35-44		81 (28.4)	71 (24.7)
>=45		33 (11.6)	61 (21.3)
Mean (SD)		33.4 (10.6)	36.7 (12.5)
Religion – no. (%)			
Christian		269 (94.7)	260 (90.6)
Other		15 (5.3)	27 (9.4)
Education – no. (%)			
Did not complete primary		21 (7.4)	32 (11.2)
Completed primary		143 (50.4)	159 (55.4)
Secondary or more		120 (42.3)	96 (33.5)
Marital status – no. (%)			
Married/cohabiting		197 (69.1)	189 (65.9)
Divorced/separated/widowed		71 (24.9)	84 (29.3)
Single		17 (6.0)	14 (4.9)
HIV status - no. (%)			
Positive		104 (36.6)	

Variable	Variable parameters	Intervention group (N=286)	Control group (N=287)
Negative		135 (47.5)	
Not known		45 (15.9)	
SSQ-14 score	0 =no symptoms, 14=worst possible symptoms		
Mean (SD)		10.5 (1.4)	10.4 (1.3)
PHQ-9 score – no. (%)	0=no symptoms, 27=worst possible symptoms		
<11		98 (34.5)	119 (41.5)
>=11		186 (65.5)	168 (58.5)
WHO-DAS score – no. (%)	0 =no difficulty, 48=worst possible difficulty		
<20		244 (85.9)	254 (88.5)
>=20		40 (14.0)	33 (11.5)

Variable	Variable parameters	Intervention group (N=286)	Control group (N=287)
GAD-7 score - no. (%)	0 =no symptoms, 21=worst possible symptoms		
<=9		106 (39.7)	110 (40.9)
>=10		161 (60.3)	159 (59.1)
Suicidal ideation – no. (%)			
No		248 (86.7)	250 (87.1)
Yes		38 (13.3)	37 (12.9)
Reason for initial clinic visit – no. (%)			
Bringing sick family member to clinic		113	97
Medical condition other than HIV		66	68
HIV		49	68
Routine clinic visit		28	34
Antenatal		6	3
Depression		1	3
Other		21	14
Missing		2	0

460

461

462

Table 2: Effect of the Friendship Bench intervention on scores for common mental disorders, depression symptoms, anxiety symptoms, disability and quality of life at 6 months

Outcome	Intervention group N=260	Control group N=261	Unadjusted analysis		Adjusted analysis	
	Mean (95% CI)	Mean (95% CI)	Unadjusted mean difference (95% CI)	P value	Adjusted mean difference (95% CI)[a]	P value
Primary (continuous)						
SSQ-14 score	3.81 (3.28-4.34)	8.90 (8.33-9.47)	-5.09 (-5.86, -4.31)	<0.001	-4.86 (-5.63, -4.10)	<0.001
Non Prespecified Secondary (continuous)						
PHQ-9 score	4.50 (3.95-5.05)	11.01 (9.78-12.24)	-6.52 (-7.71, -5.33)	<0.001	-6.36 (-6.45, -5.27)	<0.001
Tertiary (continuous)						
GAD-7 score	3.74 (3.27-4.21)	9.46 (8.68-10.24)	-5.71 (-6.71, -4.71)	<0.001	-5.73 (-6.61, -4.85)	<0.001

Outcome	Intervention group N=260	Control group N=261	Unadjusted analysis		Adjusted analysis	
WHO-DAS score	4.87 (4.32-5.42)	11.05 (9.56-12.54)	-6.18 (-7.70, -4.67)	<0.001	-6.08 (-7.46, -4.71)	<0.001
EQ-5D score	0.72 (0.68-0.76)	0.85 (0.83-0.87)	0.12 (0.08, 0.71)	<0.001	0.12 (0.08, 0.17)	<0.001
	n (cluster level mean %)	**n (cluster level mean %)**	**Unadjusted prevalence ratio (95% CI)**	**p value**	**Adjusted prevalence ratio (95% CI)**	**p value**
Secondary (binary)						
PHQ-9 ≥11	35 (13.7%)	129 (49.9%)	0.28 (0.22, 0.35)	<0.001	0.28 (0.22, 0.34)	<0.001
Tertiary (binary)						
PHQ-9 diagnostic algorithm	20 (8.0%)	96 (35.8%)	0.22 (0.15, 0.33)	<0.001	0.23 (0.15, 0.33)	<0.001
GAD-7 ≥10	31 (12.2%)	123 (48.0%)	0.25 (0.18, 0.36)	<0.001	0.26 (0.19, 0.35)	<0.001

Outcome	Intervention group N=260	Control group N=261	Unadjusted analysis		Adjusted analysis	
SSQ-14 ≥9	37 (12.7%)	171 (64.0%)	0.20 (0.14, 0.28)	<0.001	0.21 (0.15, 0.29)	<0.001
WHO-DAS ≥20	9 (4.6%)	48 (17.8%)	0.26 (0.15, 0.44)	<0.001	0.27 (0.16, 0.44)	<0.001

[a]Adjusted for age, sex, HIV status, SSQ-14 score at baseline, and education.

Supplement table 1: reasons for patient ineligibility by group

	Intervention group (10 clinics)	Control group (10 clinics)	Reason for non-eligibility was not retained at clinic level (2 intervention group clinics and 2 control group clinics)
Age less than 18 years	5	7	3
Refused to allow home visits	31	14	16
SSQ score <9	499	547	504
Not literate	1	1	4
No working phone	15	18	7
Medically unfit	1	3	2
Pregnant or up to 3 months postpartum	20	10	8
Not residing in locality	58	46	24

470

Figure 1: CONSORT flow diagram of trial clinics and participants. [a]See supplement table 1 for a complete list of reasons for patient ineligibility

Figure 2: Mean and 95% confidence interval of common mental disorder severity, depressive symptoms, anxiety symptoms and disability scores at 6 months follow-up, by group and baseline severity on the SSQ-14. Interaction p-values: SSQ-14 p=0.19, PHQ-9 p=0.10, GAD-7 p=0.02, WHO-DAS p=0.02.